

I. Rejections of Claims 16 and 21-25 under 35 U.S.C. §101 and 35 U.S.C. §112, First Paragraph

The Examiner rejected Claims 16 and 21-25 under 35 U.S.C. §101 on the basis that the claimed invention has no apparent specific, substantial, or credible utility or a well-established utility. These claims were also rejected under 35 U.S.C. 112, first paragraph for the above reason.

The Examiner found Applicants previous argument that the utility asserted in the specification, e.g., use in the treatment of inappropriate immune responses such as autoimmunity and inflammation, in conjunction with extrinsic evidence supporting this assertion as not persuasive. In particular, the Examiner cannot find "... the exact degree of homology between DIRS1 and IL-20[sic, R]."

Applicants respectfully disagree with the Examiner's assertion. The extrinsic evidence submitted by Applicants, Blumberg, et al. (2001) Cell 104:9-19 ("Blumberg et al."), does in fact mention that the IL-20 receptor subunit named IL-20R $\beta$ , was in fact, previously known as DIRS1 (see, e.g., page 12, column 2, of Blumberg et al.). Further, Blumberg et al. acknowledge that DIRS1 sequence was derived from Parham, et al. WO 99/46379, the counterpart PCT filing of the present application (see page 19, column 2, of Blumberg). Therefore, Applicants submit that IL-20R $\beta$  and DIRS1 are, in fact, the same receptor subunit.

In view of the above, Applicants submit that Blumberg et al. support the utility asserted in the specification. Applicants rely on M.P.E.P §2107.02(VI) which permits rebuttal of a utility rejection by submission of printed publications to support an asserted utility. Applicants also point out that the legal standard of proof required to be shown by the evidence submitted is that it is more likely than not that the asserted utility would be considered credible by a person of skill in the art. (In re Rinehart 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976)). In particular, Applicants submit that, as noted below, there is a reasonable correlation between the asserted therapeutic utility of the present invention, e.g., modulation of inflammatory conditions, and the evidence presented.

Blumberg et al. describes upregulation of IL-20R $\beta$  (DIRS1) expression in seven psoriatic skin samples whereas normal skin samples had "... minimal to undetectable levels ..." (see, Blumberg, et al. supra, page 14, columns 1-2). It

is well known in the art that psoriasis is an inflammatory disorder of the skin, and is in fact classified as a chronic inflammatory dermatoses (see, e.g., Cotran, et al. (eds.) (1994) Pathological Basis of Disease, 5<sup>th</sup> Ed., W. B. Saunders Company, Philadelphia, PA, pages 1196-1198).

Applicants also submit a Declaration under 37 C.F.R. 1.132 by Dr. Edward Bowman to confirm Blumberg, et al. The Declaration of Dr. Bowman describes data generated after the priority date of the present application which shows a significant increase in expression of DIRS1 in psoriatic tissues versus normal skin tissue. This finding was generically described on page 68, lines 29-36, through page 69, lines 1-10, of the specification.

The Examiner further states that "tissue-specific cDNA libraries are often incomplete, or preferentially perpetuate certain clones more than others . . . thus, presence or absence in a library cannot be accepted . . ." (page 6 of Office action). Applicants respectfully disagree. Applicants submit that the screening of cDNA libraries is a well known technique in molecular biology (see, e.g., Campbell, et al. (eds.) (1999) Biology, 5th ed., Benjamin Cummings, Menlo Park, CA, pp. 370-371).

Campbell, et al., supra, states that screening a cDNA library provides "an advantage if a researcher wants to study the genes responsible for specialized functions of a particular kind of cell . . . [a]lso by making the cDNA from cells of the same type at different times in the life of an organism, one can trace changes in patterns of gene expression." (see, e.g., Campbell, et al. supra, page 371). Applicants submit that one skilled in the art would reasonably believe that presence or absence in a library may be accepted as preliminary evidence of differential expression.

Taken together, Applicants believe the present invention is supported by credible, substantial, and specific utility, and that the skilled artisan would know how to use the claimed invention. As such, the rejections of Claims 16 and 21-25 under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph are overcome. Withdrawal of these rejections is respectfully requested.

### Conclusion

Applicants' current response is believed to be a complete reply to all the outstanding issues of the latest Office Action. Further, the present response is a bona fide effort to place the application in condition for allowance or in better form for appeal. Accordingly, Applicants respectfully requests reconsideration and passage of the amended claims to allowance at the earliest possible convenience. Should the Examiner deem allowance inappropriate at this time, Applicants respectfully request an interview be granted with the undersigned to consider any issues.

Respectfully submitted,

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Enclosures:

1. Declaration under 37 C.F.R 1.132
2. Curriculum vitae of Dr. Edward Bowman
3. Blumberg, et al. (2001) Cell 104:9-19
4. Cotran, et al. (eds.) (1994) Pathological Basis of Disease, 5<sup>th</sup> Ed., W. B. Saunders Company, Philadelphia, PA, pages 1196-1198
5. Campbell, et al. (eds.) (1999) Biology, 5th ed., Benjamin Cummings, Menlo Park, CA, pp. 370-371.